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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,483	09/15/2003	Robin Fong	GC775-2	2423

7590 02/28/2006

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,483	FONG ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,6-13 and 15-19* is/are allowed.

6)☒ Claim(s) *3,5,14 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Paragraph [01] of the specification and the declaration filed January 23, 2004 indicate that Applicants only intend to claim priority based upon provisional application 60/411,537. However, the filing receipt indicates that Applicants have also claimed priority based upon provisional application 60/411,540. Applicants are request to confirm their intended priority claim so that appropriate correction can be taken.

2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

3. The abstract of the disclosure is objected to because it is insufficiently detailed. The abstract should recite that a preferred protein of interest is an immunoglobulin or fragment thereof, and should recite that the chromatography involves the use of hydrophobic charge induction chromatography. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 9, line 14, of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the broth" in claim 3. It is believed that claim 3 should instead depend upon claim 2.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The pH ranges recited in claims 14 and 15 are not recited in the specification. The number of steps range recited in claim 17 is not recited in the specification. The method of claim 25, in which an immunoglobulin is not required to be purified from its fusion analog, is not recited in the specification.

7. Instant claims 1-4, 6-13, 16, 18, and 19 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/411,537 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

Instant claims 5, 14, 15, 17, and 20-25 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/411,537 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a protein which is a peptide concatamer or which is a fragment of an enzyme, a fragment of a peptide concatamer, a fragment of a hormone, a fragment of a growth factor, a fragment of a receptor, or a fragment of a vaccine; does not disclose the pH gradient ranges recited in claims 14 and 15, and does not disclose that the pH gradient can range from low to high or from high to low; does not disclose a step pH gradient comprising between two and six steps; does not disclose HCIC binding and elution done in a batch process; does not disclose HCIC resin in a

packed column, in an axial flow column, in a radial flow column, or in an expanded bed column; and does not disclose purifying an immunoglobulin wherein the immunoglobulin is not required to be purified from its fusion analog.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v.

Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

9. Claims 5, 14, 20-22, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Power et al (U.S. Patent Application Publication 2004/0018573). Power et al teach separating free IgG1 from glucoamylase-IgG1 fusion proteins by hydrophobic charge induction chromatography. In the purification method, the fermentation broth is clarified, its pH is adjusted to 8.2, it is applied to the HCIC column, the column is washed, and the free IgG1 is eluted by incrementally decreasing the pH ultimately down to 2.5. See paragraph [0160].

The disclosure of Power et al relied upon in the above rejection is not disclosed in Power et al's provisional application 60/373,889. Accordingly, Power et al is not available as prior art under 35 U.S.C. 102 against any of the instant claims which are entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/411,537.

10. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being obvious over Power et al (U.S. Patent Application Publication 2004/0018573) as applied against claims 5, 14, 20-22, and 25 above, and further in view of Burton et al (U.S. Patent No. 5,652,348). Power et al do not teach practicing the HCIC in a radial flow column or an expanded bed column. Burton et al is the basic patent covering hydrophobic charge induction chromatography, and teaches in claims 22 and 23 that the chromatography can be carried out in radial flow and expanded bed columns. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to practice the HCIC chromatography of Power et al in the radial flow or expanded

bed column as taught by Burton et al because Burton et al teach these particular columns to have generalized utility in HCIC.

11. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by the Guerrier et al article (Bioseparation, Vol. 9, pages 211-221). The Guerrier et al teach purifying an antibody from ascite fluids by hydrophobic charge induction chromatography. The ascite fluid containing the antibody is diluted twice with loading buffer having a pH of 8 (which corresponds to Applicants' pH adjustment step); it is applied to a HCIC column; the column is washed; and the antibody is then eluted from the column using an acetate buffer of pH 4.0. See, e.g., the Abstract and page 213, column 1 through column 2, line 4.

12. Claims 1, 2, 4, 6-13, and 15-19 are allowed. Claim 3 is would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The prior art of record does not teach separating a protein of interest from its fusion analog by hydrophobic charge induction chromatography. Although purification of fusion proteins in general by HCIC is taught by the prior art (see, e.g., Fahrner et al (U.S. Patent Application Publication 2003/0229212) at Example 1; and the Guerrier et al article (J. Chrom. B, Vol. 755, pages 37-46) at page 45, column 1, first full paragraph, and column 2, first paragraph), the prior art of record does not teach or suggest that HCIC is capable of separating two proteins which are so closely related in structure, i.e. which differ only in the presence or absence of a signal peptide/secretory sequence.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 21, 2006